PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	16 MAR 2006
Applicant's or agent's file reference K15-017PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US04/34142	15 October 2004 (15.10.2004)	17 October 2003 (17.10.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A01N 25/00; A23K 1/18 and US Cl.: 424/405,438

Applicant

ROBERT D. KROSS ET AL

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	23 January 2006 (23.01.2006)	Abigail M. Cotton Telephone No. (571) 272-8779

Form PCT/ISA/237 (cover sheet) (April 2005)

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International application No.
PCT/US04/34142

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-51	YES
	Claims NONE	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-51	NO
Industrial applicability (IA)	Claims 1-51	YES
	Claims NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1-51 meet the criteria set out in PCT Article 33(2), because the prior art does not teach the specific method of disinfecting mammalian teat skin and the specific disinfecting compositions as claimed.

Claims 22-28, 30, 32-41, 43-48 and 51 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent Application Publication No. 2002/01367650 to Benjamin et al, published September 26, 2002.

Benjamin et al. teaches a topical medicament for the treatment of bacterial, viral or fungal conditions (see abstract, in particular.) Benjamin et al. teaches that the topical composition can be in the form of on a cream or an ointment, and may also be present for administration in liquid form (see paragraph 0029, in particular.) Benjamin further teaches that the composition comprises a nitrite such a sodium nitrite (see paragraph 0038, in particular) and an organic acid such as ascorbic acid, citric acid, etc, which are protic acids (see paragraph 0037, in particular.) Benjamin et al teaches that an amount of the sodium nitrite may be from 0.5% to 30%, which overlaps with the range recited in claim 22. Benjamin et al. teaches that the acid is included to provide a low pH (see paragraph 0037, in particular.)

Regarding the specific amounts of nitrous acid and protic acid, as recited in claim 22, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amounts of the components to provide desired properties, according to the guidance provided by Benjamin et al. Regarding the antimicrobial activity being maintained for at least 48 hours, it is considered that as Benjamin et al. renders the claimed composition obvious, the properties of such a composition are also obvious. Accordingly, claim 22 is obvious over the teachings of Benjamin et al.

Regarding claims 23-24, Benjamin et al. teaches providing acids such as citric acid that is an alpha-hydroxy acid that meets the structural limitations as claimed, and teaches providing a low pH (see paragraphs 0037-0038, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amounts of the components to provide desired properties, according to the guidance provided by Benjamin et al.

Regarding claim 25, Benjamin et al. teaches that the nitrides can be sodium nitrite (see paragraph 0038, in particular.) Regarding claim 26, it is noted that the recitation "teat dip" is an intended use of the composition, and thus does not impose a structural limitation on the claim, and thus is taught by Benjamin et al. Regarding claim 27, Benjamin et al. teaches that the composition can comprise conventional topical carriers (see paragraphs 0029 and 0041, in particular.) Accordingly, it would have been obvious to one of ordinary skill in the art to provide the conventional carrier that is a gel.

Regarding claim 28, Benjamin et al. renders obvious the composition comprising nitrous acid, from a metal nitrite, and an alpha-hydroxy acid in the amounts as recited, as discussed above. Regarding the claimed change in pH of the composition over time and the cidal activity of the composition against microorganisms, as is also recited in claims 32-33, it is considered that as Benjamin et al. renders the claimed composition obvious, the properties of such a composition are also obvious. Accordingly, claims 28 and 32-33 are obvious over

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the teachings of Benjamin et al.

Regarding claim 30, Benjamin et al. teaches citric acid which is an alpha-hydroxy acid that meets the structural limitations of the claim. Regarding claim 34, Benjamin et al. teaches the composition can be applied with an adhesive layer (see paragraph 0051, in particular.) Regarding claims 35, Benjamin et al. teaches providing metal nitrites such as sodium nitrite (see paragraph 0038), and thus teaches generating the nitrous acid. Regarding claim 36, it is noted that the recitation "used as a liquid teat dip" is an intended use of the composition, and thus does not impose a structural limitation on the claim, and thus is taught by Benjamin et al. Regarding claim 37, Benjamin et al. teaches that the composition can comprise conventional topical carriers (see paragraphs 0029 and 0041, in particular.) Accordingly, it would have been obvious to one of ordinary skill in the art to provide the conventional carrier that is a gel.

Regarding claim 38, Benjamin et al. teaches a method of sterilizing a substrate (object) by applying the composition thereto (see paragraph 0056-0061, in particular.) Regarding claim 41, Benjamin et al. teaches that the nitrite can comprise from 0.5 to 30% of the composition (see paragraph 0039, in particular), and thus teaches an amount that meets the range limitation of the claim. Regarding claims 43 and 45, Benjamin et al. teaches a mouthwash comprising the composition (see paragraphs 0083-0084, in particular), and thus also teaches applying to mammalian tissue. Regarding claim 44, Benjamin et al. exemplifies applying a composition over a period of 24 months (see paragraphs 0089-0090, in particular.) Regarding claim 46, Benjamin et al. teaches that a conventional carrier for the composition can be provided (see paragraphs 0029-0041, in particular), accordingly it is considered obvious to provide carrier that allows for spraying of the compositions.

Regarding claims 39 and 47-48, Benjamin et al. teaches that the composition is an antimicrobial composition (disinfectant (see abstract, in particular), and teaches the topical application, such as in the removal of warts or for a mouthwash (see Examples 6-8, in particular.) Accordingly, Benjamin et al. teaches a disinfectant for mammalian tissue. Regarding claims 40 and 51, Benjamin et al. teaches that the composition can sterilize dentures (see paragraph 0016, in particular) which can be a metal substrate.

Claim 29 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of U.S. Patent No. 5,628,959 to Robert D. Kross, issued May 13, 1997.

Benjamin et al. is applied as discussed above, and teaches a composition for disinfecting comprising an acid such as lactic acid, citric acid or tartaric acid, and a nitrite. Benjamin et al. does not specifically teach that the acid is an inorganic acid as recited in the claims.

Kross discloses that both organic acids such as lactic acid, citric acid or tartaric acid, as well as inorganic acids such as nitric, hydrochloric, sulfuric can phosphoric acids are useful as protic acids or a combination of protic acids for sterilizing and disinfecting compositions (see abstract and column 3, line 63 though column 4, line 4, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the inorganic acid of Kross in the composition of Benjamin et al., because Kross teaches the suitability and interchangeability of the claimed acids and the organic acids named by Benjamin et al. for the purposes of acidifying sterilizing compositions.

Claims 1-12, 15-21, 31, 42 and 49-50 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent Application Publication No. 2002/01367650 to Benjamin et al, published September 26, 2002, as discussed for claims 22-28, 30, 32-38, 41 and 43-48 above, in view of U.S. Patent No. 6,630,458 to Larm et al, issued October 7, 2003.

Benjamin et al. is applied as discussed above, and teaches an antimicrobial composition for topical use that can be in liquid form or other conventional carrier (see paragraph 0029, in particular), and comprises an acid such as a citric acid, which is a protic alpha hydroxy acid, and a nitrite such as sodium nitrite (see paragraphs 0037-0038, in particular.) Benjamin et al. teaches that the nitrite can comprise from 0.5% to 30% of the composition (see paragraph 0039, in particular.) Regarding the specific amount of nitrous acid that is formed, it is noted that as Benjamin et al. teaches providing the nitrite that generates the nitrous acid, it would have been obvious to one of ordinary skill in the art to vary and/or optimize the amount of nitrite, and thus the amount of nitrous acid, to provide desired properties. It is furthermore noted that the transitional phrase "consisting essentially of" is being interpreted as being equivalent to "comprising" for the purposes of applying prior art.

Benjamin et al. does not specifically teach disinfecting mammalian teat skin with the composition by contacting with the composition, as recited in the claim.

Larm et al. teaches hat antibacterial compositions are used as teat dipping compositions with lactating animals, such as cows (see abstract and column 1, lies 5-65, in particular.) Larm et al. also teaches that a suitable carrier can be an aqueous one, and even pure water (see column 3,lines 59-61, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the topical antimicrobial composition of Benjamin et al. in the teat dipping method of Larm et al, because Benjamin et al. teaches the composition has antimicrobial properties and is suitable for topical and even oral application, and Larm et al. teaches that the teat dipping compositions are desirably antimicrobial. Thus, one of ordinary skill in the art would have been motivated to combine the teachings with the expectation of providing a suitable teat dipping composition.

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Regarding claims 3-4, Benjamin et al. teaches providing citric acid, which is an organic acid, and sodium nitrite (see paragraphs 0037-0038, in particular.) Regarding the amount of nitrite as recited in claim 2, Benjamin teaches a preferred range of nitrites (see paragraph 0039, in particular), and it is considered that it would have been obvious to one of ordinary skill in the art to vary and/or optimize the amount of nitrite to provide desired properties.

Regarding the pKas as recited in claims 5-7, the formula recited in claim 8, the acid amounts recited in claim 9 and the pH recited in claims 10-12, Benjamin teaches citric acid that meets the limitation of the structure, and also teaches other acids such as ascorbic acid and formic acid and teaches that the pH of the composition is desirably low (see paragraph 0037, in particular). Accordingly, it is considered that it would have been obvious to one of ordinary skill in the art to vary and/or select the acid and or amount of acid to provide solution with an acid with a pKa that provide desired properties, such as the desired pH.

Regarding claim 15, Larm et al. teaches that the teat dipping composition can comprise a viscosity controlling agent (gelling agent) (see column 3, lines 60-66, in particular.) Regarding the limitation recited in claim 16 that the composition "remains on the teat upon drying of the composition," it is considered that as Benjamin et al. and Larm et al. render the composition obvious, the properties of such a composition are also rendered obvious by the prior art teachings. Regarding claim 17, Larm et al. teaches that the amount of viscosity controlling agent provided is selected in accordance with the desired viscosity of the composition (see column 3, lines 60-66, in particular.) Accordingly, it is considered that it would have been obvious to one of ordinary skill in the art to vary and/or optimize the amount of viscosity controlling agent provided in the solution to provide desired teat disinfection properties.

Regarding the antimicrobial activity as recited in claims 18-20, it is considered that as Benjamin et al. and Larm et al. render the composition obvious, the properties of such a composition are also rendered obvious by the prior art teachings. Regarding claims 21, Larm et al. teaches treatment of cows (see column 1, lines 10-25, in particular.)

Regarding claims 31 and 42, Benjamin et al. and Larm et al. teach the composition for treating mammalian teat skin as discussed above. Larm et al. further teaches that a viscosity controlling agent (thickener) can be provided in the composition (see column 3, lines 60-67, in particular), as claimed. Regarding claim 49-50, Larm et al. teaches the treatment of cow teats (see column 1, lines 10-25, in particular.)

Claims 13-14 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of U.S. Patent No. 5,628,959 to Robert D. Kross, issued May 13, 1997.

Benjamin et al. and Larm et al. are applied as discussed above, and teach a method and composition for disinfecting comprising an acid such as lactic acid, citric acid or tartaric acid, and a nitrite. Benjamin et al. and Larm et al. do not specifically teach that the acid is an inorganic acid as recited in the claims.

Kross discloses that both organic acids such as lactic acid, citric acid or tartaric acid, as well as inorganic acids such as nitric, hydrochloric, sulfuric can phosphoric acids are useful as protic acids or a combination of protic acids for sterilizing and disinfecting compositions (see abstract and column 3, line 63 though column 4, line 4, in particular.) Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the inorganic acid of Kross in the composition and method of Benjamin et al. and Larm et al, because Kross teaches the suitability and interchangeability of the claimed acids and the organic acids named by Benjamin et al. for the purposes of acidifying sterilizing compositions.

Claims 1-51 meet the criteria set out in PCT Article 33(4), and thus the claims have industrial applicability because the subject matter claimed can be made or used in industry.